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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,085	03/04/2002	George N. Lambrou	OP/4-31902A/USN	4270

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,085	LAMBROU ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *15 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 5-6, 9-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114. Claims 1-2, 5-6 and 9-10 are currently pending for prosecution on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 9-10 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The present claims are drawn to a method of treatment disease condition selected from pulmonary hypertension, asthma, interstitital cystitis, urinary incontinence and other urogenital disorders, ischemic bowel disease, gastrointestinal motility disorders, arrhythmias, peripheral vascular disease, congestive heart failure, dysmenorrheal, angina and alopecia with the administration of the claimed composition.

The instant specification provides assay to test the compound, namely unoprostone isopropyl, in vitro and discloses that unoprostone isopropyl exhibits Maxi K channel opening activity. However, there is no demonstrated correlation that the tests and results apply to all of

the disorders embraced by the instant claims. The specification provides insufficient written description to support the treatment of entire scope disease conditions encompassed by the claim.

Vas-Cath Inc. Mahurkar, 19 USPQ2d 1111, makes clear the "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the activity of opening potassium channels in the cell membranes or treating the specific conditions or diseases (i.e., hypertension, ocular hypertension, pulmonary hypertension, asthma) that may be mediated by Maxi-K channel, the skilled artisan cannot envision which disease conditions would be responded to potassium channel opening activity of unoprostone isopropyl. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the

inventor invented the claimed invention." *Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966(1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)* ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 recite the limitation "in need of such treatment " in claims 1 and 2, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claims 9-10 recite the limitation "said condition or disease state" in claims 9 and 10, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed (WO 98/41208).

The claims read on a method for opening potassium channels in the cell membranes of a mammal in need of such treatment comprising administering to the mammal an effective amount of a compound of the formula (in claim 1 and claim 2), namely unoprostone isopropyl.

Reed teaches the ophthalmic administration of isopropyl unoprostone for the treatment of ocular hypertension, wherein said isopropyl unoprostone is administered within the dosage range of about 0.001 to about 0.30 weight percent (Examples 1-3). Examples 1-3, especially Table I, shows the efficacy of about 0.12% to about 0.18% isopropyl unoprostone in lowering intraocular pressure wherein about 30 microliters of the formulation were instilled into the eye of a rabbit.

Although Reed is silent about the activity of isopropyl unoprostone in opening potassium channels in the cell membranes of a mammal, such property or characteristics deems to be inherent to the prior art method of treating ocular hypertension. Especially in light of the instant disclosure (page 8, line 25 thru page 9, line 2; page 9, lines 7-12 and 29; page 10, line 3), the prior art method directing the administration of composition comprising isopropyl unoprostone inherently possessing a therapeutic effect for the same ultimate purpose (i.e., hypertension, ocular hypertension or glaucoma) in overlapping dosage amounts as disclosed by Applicants anticipates Applicants' claims even absent explicit recitations of the mechanism of action.

5. Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueno et al. (US 5254588).

Ueno teaches a use of the claimed compounds represented by the formula (i.e., 15-ketoprostaglandin) for the treatment of pulmonary dysfunction including pulmonary hypertension and asthma (column 2, lines 15-39).

Although Ueno is silent about the activity of the claimed compounds represented by the formula in opening potassium channels in the cell membranes of a mammal, such property or characteristics deems to be inherent to the prior art method of treating pulmonary hypertension and asthma. Especially in light of the instant disclosure (page 8, line 25 thru page 9, line 2; page 9, lines 7-12 and 29; page 10, line 3), the prior art method directing the administration of said composition inherently possessing a therapeutic effect for the same ultimate purpose (i.e., pulmonary hypertension and asthma) in overlapping dosage amounts as disclosed by Applicants anticipates Applicants' claims even absent explicit recitations of the mechanism of action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-2 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-8 of copending Application No.10/838080. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because instantly claimed underlying mechanism of the action must be inherently presented in the copending application. The copending application directing the administration of compound(s) falls under the definition of the formula of the instant invention inherently possessing a therapeutic effect for the same ultimate purpose (i.e., treatment of glaucoma) as disclosed by Applicants (see page 10, line 3 of the instant specification) anticipates Applicant's claims even absent explicit recitations of the mechanism of action. Therefore, the copending application makes obvious the instantly claimed invention.

Conclusion

7. No Claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614